DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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June 13, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

IN REPLY REFER TO: SEA 02-49

Mr. Paul F. Burg, President
Integra Chemical Company
710 Thomas Avenue Southwest
Renton, Washington 98055

WARNING LETTER

Dear Mr. Burg:

During an inspection of your facility on May 16-21, 2002, FDA Investigators Carl A. Anderson and Dawn E. Barkans documented the failure of your firm to repack active pharmaceutical ingredients (APIs) in conformance with Current Good Manufacturing Practice (CGMP) [21 C.F.R. Parts 210 and 211]. At the conclusion of the inspection, a FDA Form 483, Inspectional Observations, was presented to you.

These deviations cause these APIs to be adulterated within the meaning of Section 501(a)(2)(B) [21 U.S.C. § 351(a)(2)(B)], of the Federal Food, Drug, and Cosmetic Act (the Act). This section of the Act requires that all drugs be manufactured, processed, packed, and held in accordance with CGMP. No distinction is made between active pharmaceutical ingredients and finished pharmaceuticals. Failure to comply with CGMP constitutes a failure to comply with the Act.

Significant examples of failure to comply with Current Good Manufacturing Practices in the repackaging of APIs by your firm include, but are not limited to, the following:

1. The room used for repackaging APIs is not maintained in a clean and sanitary condition nor is it of suitable construction. For example: the ceiling tiles are porous; damaged ceiling tiles have been replaced with cardboard; the floor is cracked and in need of repair; the entry to the room has carpeting; the opening containing the ventilation fan is sealed with cardboard; and the window blinds have visible dirt adhering to the slats [21 C.F.R. §§ 211.42(a) and 211.56(a)].

2. Ventilation of the repackaging room is not adequate in that it is not designed and constructed to minimize risks of contamination and cross-contamination. For example, a window fan is used for ventilation to the adjacent warehouse area and cardboard is used to seal the window frame in which this fan is installed [21 C.F.R. § 211.46(a)].

3. Bulk APIs are not stored in the warehouse under appropriate conditions of temperature so that the identity, strength, quality, and purity of the drug products are not affected. Your firm's written procedures specify that the warehouse is maintained at 50°-70° F but there is no documentation that the drug products are stored within this temperature range [21 C.F.R. § 211.142(b)].

4. A reserve sample representative of each lot of each API repackaged by your firm is not retained [21 C.F.R. § 211.170(a)].

5. There are no written procedures describing the handling of all written and oral complaints regarding drug products repackaged by your firm [21 C.F.R. § 211.198].

6. There are no written procedures for the holding, testing, and reprocessing of returned drug products [21 C.F.R. § 211.204].

The identification of violations above is not intended to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure adherence with the requirements of the Federal Food, Drug, and Cosmetic Act and that your API products are repacked and held according to current good manufacturing practice. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

Please advise this office within fifteen days of your receipt of this letter as to the specific actions you have taken or intend to take to correct these violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be directed to the attention of Thomas S. Piekarski, Compliance Officer, at the address noted on the letterhead.

Sincerely,

Charles M. Breen
District Director